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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,304	09/24/2003	Bronislava Gedulin	18528.643 / 0101-UTL-0	8486

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EXAMINER	
WINSTON, RANDALL O	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,304	GEDULIN ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on 12/03/2006.

Examiner has acknowledged that claims 21-22 have been added.

Claims 1-20 and newly added claims 21-22 are under examination.

ELECTION BY ORIGINAL PRESENTATION

Newly submitted claims 21-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally presented claims (i.e. 1-20) were examined over the art insofar as a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject (i.e. human) comprising administering to said subject an effective amount of the amylin analog of 25,28,29 Pro-h-amylin, an analgesic and a pancreatic enzyme. However, newly presented claims 21 and 22 are drawn to a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject (i.e. human) comprising administering to said subject an effective amount of different amylin analog from the amylin analog of 25,28,29 Pro-h-amylin because claims 21 and 22 amylin analog genus (SEQ ID NO:2) claims contained many different species within it amylin analog whereas SEQ ID NO:2 could comprise of many variations of an amylin analog. (please note: if claims 1-20 and 21-22 were originally presented, examiner would have done a restriction between claims 1-20 and claims 21-22 because claims 21-22 amylin analog (SEQ ID NO:2) requires an election of species requirement which could have been different from the claimed and originally examined amylin analog of

25,28,29 Pro-h-amylin. The consideration for patentablility is different in each case because the claimed and/or original examined amylin analog of 25,28,29 Pro-h-amylin is patentability distinct from the claims 21-22 amylin analog (SEQ ID NO:2) which requires an election of species whereas SEQ ID NO:2 could comprise of many variations of an amylin analog.) Thus, it would have been an undue burden to examine two patentable distinct inventions (i.e. and/or compositions) in one application. Thus, the two inventions are unrelated as two distinct methods because both methods utilize different claimed compositions to obtain its preamble objective. Since applicant has received an action on the merits for the originally presented invention of claims 1-20, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-22 are withdrawn from consideration as being directed to a nonelected invention. See 27 CFR 1.142(b) and MPEP 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-16 and 18-20 as amended still stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject comprising administering to said subject an effective amount of the amylin analog

25,28,29 Pro-h-amylin, the specification does not enable any person in the art for preparing a method for treating pancreatitits and/or relieving the pain caused by pancreatitis comprising administering all amylin analogs.

In Applicant's response on 12/03/2006, Applicant's argues, the specification, including examples, illustrates the operation of the invention. Amylin analogs and assays for identifying amylin analogs with amylin agonist activity are described in the specification and known in the art. Following these teachings, using amylin analog other than 25,28,29 Pro-h-amylin is not seen to involve undue experimentation. Thus, Applicants respectfully submit that the specification adequately teaches the skilled artisan how to make and use, i.e., enables, the claimed invention.

Applicant argument is not found persuasive because claims 1-16 and 18-20 still stand rejected under 35 U.S.C. 112, first paragraph, for the same reasons set forth in examiner's non-final office action of 06/14/2006. Although Applicant argues that amylin analogs used in the present invention are described in the specification and is well known in the art, Applicant specification does not adequately teach the skilled artisan how to make and use all claimed amylin analogs by applicant. For example, Applicant has reasonably demonstrated on pages 24-30 (examples 1-3, especially example 2) of the specification a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject comprising administering to said subject an effective amount of the amylin analog of 25,28,29 Pro-h-amylin. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for treating pancreatitits and/or relieving the pain caused

by pancreatitis comprising administering all amylin analogs. Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 and 18-20 as amended still stand rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (US 5,677,279) in further view Braganza et al. (US 5196402) and Jorgensene et al. (US 4,370,317).

In Applicant's response on 12/03/2006, Applicant's argues Young describes the use of an amylin or amylin agonist for treating agonist for treating or preventing pain. Young does not teach or suggest the use of an amylin or an amylin agonist for treating pancreatitis. Moreover, Braganza nor Jorgensen does not remedy Young's teachings because neither Braganza nor Jorgensen describes treating the pain of pancreatitis. Neither Braganza nor Jorgensen mentions or suggest the use of an amylin or an amylin agonist for use in treating pancreatitis. Therefore, alone or combined, the cited references do not teach or suggest that an amylin or an amylin analog can be used to treating pancreatitis.

Applicant argument is not found persuasive because claims 1-16 and 18-20 still stand rejected under 35 U.S.C. 103(a) for the same reasons set forth in examiner's non-

final office action of 06/14/2006. Therefore, alone or combined, the cited references do teach or suggest that an amylin or an amylin analog can be used to treating pancreatitis because it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the same amylin analog as the claimed invention's amylin analog of 25,28,29 Pro-h-amylin and an analgesic to treat the painful disorder of pancreatitis in a mammalian subject because Young teaches that the amylin analog of 25,28,29 Pro-h-amylin and an analgesic treats painful disorders and Braganza teaches that pancreatitis is a painful disorder. Thus, when the same amylin analog as the claimed invention's analog of 25,28,29 Pro-h-amylin in combination with an analgesic are administered to a mammalian subject for treating pain, it would intrinsically treat the painful disorder of pancreatitis within a mammalian subject when treating the pain. Moreover, it would have been obvious to modify Young's administration's method of administering the same amylin analog as the claimed inventions amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to include the teaching of Young which states a pancreatic enzyme is well known in the art for treating pancreatitis because the above combined teachings would create an improve method of administering of treating the painful disorder of pancreatitis in a mammalian subject. The adjustments of other conventional working conditions (i.e. the substitution of the administration of one mammalian subject for another), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1-18-07

SUSAN COE HOFFMAN
PRIMARY EXAMINER